Remarks

The July 5, 2005 Official Action has been carefully considered. In view of the amendment submitted herewith and these remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that an initial, shortened statutory response period of three months was set in the July 5, 2005 Official Action. The initial due date for response, therefore, is October 5, 2005. The present request for reconsideration is being filed before the expiration of the initial response period.

The July 5, 2005 Official Action notes an objection to claim 18 with regard to the misspelling of the word "imaging". In accordance with the present amendment the spelling of the word imaging in claim 18 has been corrected, thus overcoming the examiner's objection.

Turning to the substantive aspects of the July 5, 2005 Official Action, claims 1-4 and 10-13 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by the disclosure of U.S. Patent 5,096,694 to Quivy et al. The Quivy et al. patent relates to compounds which are disclosed as being useful for radiotherapy or imaging of cancer. The compounds specifically mentioned in the Quivy et al. patent are nucleoside analogs, particularly thymidine analogs which are radiolabeled with iodine 123, and susceptible of becoming fixed or passing close to the DNA of target cells. See the Abstract of the Quivy et al. patent.

In addition, claims 1-4 and 10-18 have been rejected under 35 U.S.C. §103 as allegedly obvious over the Quivy et al. patent. According to the examiner, it would have been prima facie obvious to a person of ordinary skill in the art at the time the present invention was made, based on the disclosure of the Quivy et al. patent, to administer the compound of the invention intravenously, intraperitoneally, or within a period of days of years. The examiner further contends in this regard that a person of ordinary skill in the art would have been motivated to arrive at the present invention, as outlined at page 4 of the official action, because the routes of administration in applicants' claims are purportedly well known in the art and the nature of cancer treatment requires an adjustment to this administration over daily or yearly period.

The July 5, 2005 Official Action also indicates that claims 5-9 are allowed. Each of claims 5-9 is directed to a specific radiolabeled conjugate comprising thymidine substituted with a radionuclide and linked to dihydrotestosterone (DHT).

The foregoing claim objection and prior art rejections constitute all of the grounds set forth in the July 5, 2005 Official Action for refusing the present application.

For the reasons presented below, applicants respectfully submit that the aforementioned prior art rejections are fatally flawed and, therefore, cannot be maintained. These grounds of rejection are respectfully traversed.

A. The Quivy et al. Patent Fails to Anticipate the Radiolabeled Conjugate of Claims 1-4 and the Cancer Treating Method of claims 10-13

Rejections under 35 U.S.C. §102 are proper only when the claimed subject matter is identically disclosed or described in the reference cited as evidence of lack of novelty. In re Arkley, 172 U.S.P.Q. 524 (C.C.P.A. 1972). Applying this rule of law to the present case, the 35 U.S.C. §102(b) rejection of claims 1-4 and 10-13 based on Quivy et al. is improper because the subject matter of the rejected claims is nowhere identically disclosed or described in the cited reference.

The Quivy et al. patent describes derivatized nucleoside analogs, in which the substituents, e.g. acetyl and benzoyl, serve no purpose other than as protective groups (see column 2, lines 34-35 of the Quivy et al. patent). Applicants' conjugates, by contrast, have at least one DHT substituent which serves a distinct role in the biological function of the conjugate. The DHT substituent allows targeting of the specific receptor in the cancer cell and allows the retention of the freed cytotoxic agents inside the cell until the cell is ready to make or repair its DNA.

Moreover, there is no disclosure in the Quivy et al. patent related to nucleotides, i.e., compounds of the general structure proposed in the reference, but having a phosphate substituent at the 5'-position. The Quivy et al. patent is concerned only with nucleoside analogs with "unnatural"

substituents. The phosphate groups are part of the structure of nucleotides, i.e., they are not "unnatural".

Applicants' conjugates are considered unique because there is an active transport mechanism involved - the receptor aids in the transport of the conjugate - and as such the presence of negative charges will not prevent the drug from crossing the cell membrane and entering the cancer cell. This mechanism also allows for an enhanced specificity and selectivity of the claimed conjugates i.e., the only cells that will be killed are those that (i) have a specific receptor and (ii) are making DNA.

The examiner appears to have overlooked the recitation in applicants' claim 1 that at least one (1) of the R and R' substituents comprise a DHT moiety. One searches the disclosure of the Quivy et al. patent in vain for any disclosure of a substituent comprising a DHT moiety. Thus, claims 1-4 and 10-13 should be allowable based on the same rationale that brought about the allowance of claims 5-9. Claims 2-4, which depend from claim 1, and claims 10-13, which are directed to a method of using the radiolabeled conjugate of claim 1 for treatment of a malignant tumor, should be allowable over the Quivy et al. patent for at least the same reasons that claim 1 is allowable over the Quivy et al. patent.

Inasmuch as the Quivy et al. patent fails to identically disclose or describe all of the claim recitations of applicants' claims 1-4 and 10-13, the 35 U.S.C. §102(b) rejection of those claims based on the Quivy et al. patent is

untenable and should be withdrawn.

B. The Quivy et al. Patent Fails to Render Obvious the Subject Matter of Claims 1-4 and 10-18

All claims recitations must be considered in determining non-obviousness under 35 U.S.C. §103. In re Sather, 181 U.S.P.Q. 36 (C.C.P.A. 1974). It has long been held that when the examiner disregards specific claim recitations that distinguish over the prior art, the rejection is improper and will be overturned. In re Glass, 176 U.S.P.Q. 489 (C.C.P.A. 1973).

In the present case, the examiner has clearly erred in rejecting applicants' claims 1-4 and 10-18 as obvious in view of the Quivy et al. patent. All of the claims thus rejected call for a radiolabeled conjugate of the structure set out in claim 1 in which at least one (1) of the R and R' substituents comprises a DHT moiety. The Quivy et al. patent, on the other hand, provides no disclosure which would lead anyone of ordinary skill in the art to the radiolabeled conjugates claimed by applicants herein, or to the use of such conjugates for the treatment of a malignant tumor. It has long been held that silence in a reference is not a proper substitute for an adequate disclosure of facts from which a conclusion of obviousness may justifiably follow. In re Burt, 148 U.S.P.Q. 548 (C.C.P.A. 1966).

In summary, given the absence of any teaching or suggestion in the Quivy et al. patent of a radiolabeled conjugate

comprising DHT, the present 35 U.S.C. §103 rejection of claims 1-4 and 10-18 based on the Quivy et al. patent is untenable and should be withdrawn.

In view of the present amendment and the foregoing remarks, it is respectfully urged that the objection and rejections set forth in the July 5, 2005 Official Action be withdrawn and that this application be passed to issue, and such action is earnestly solicited.

Respectfully submitted,

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